REMARKS

Status of the Claims

Applicants thank Examiner Rawlings for entering the amendment filed June 17, 2004. Claims 33-48 were added. Claims 40-48 have been withdrawn from consideration. Claims 33-39 are pending. Claims 33-39 have been rejected. Claims 37 and 39 have been objected to. Claims 33, 37 and 39 have been amended. Applicant respectfully requests reexamination and reconsideration of the above-identified amended application in view of the following amendments and remarks. No new matter has been added by way of amendment.

Request for Withdrawal of Finality

Applicant respectfully requests that the Examiner withdraw the finality of the Office Action dated September 23, 2004.

The Examiner states that the Applicant's amendment necessitated the new ground(s) of rejection. The Applicant's respectfully disagree. The Applicant's amended claims are substantially similar to those claims 1-16 cancelled via amendment filed June 7, 2004. A second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed. (see MPEP 706.07(a)). For this independent reason, Applicant requests that the finality of the present Office Action be withdrawn.

Second, the Examiner subjected the amended claims to a restriction requirement, subsequently withdrawing Claims 40-48 from prosecution. By making the present Office Action final, the Examiner does not provide the Applicant's a fair opportunity to address these claims. For this independent reason, Applicant requests that the finality of the present Office Action be withdrawn.

Lastly, in the present Office Action, the Examiner rejected claims 33-39 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. This rejection for lack of written description is a new rejection. For this independent reason, Applicant requests that the finality of the present Office Action be withdrawn.

Claim Objections

Claims 37 and 39 were objected to because of inconsistent language. Claims 37 and 39 have been amended, therefore Applicants respectfully request that the Examiner withdraw the objection.

The Rejections of Claims 33-39 Under 35 U.S.C. §112, First Paragraph Should be Withdrawn:

Claims 33-39 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claim 33 has been amended to recite "breast cancer cells", thus obviating the rejection of that claim. Claim 34 was rejected by the Examiner because the specification does not provide specific written support for the term "non-percutaneous". The Applicants respectfully traverse this argument. The Examiner states that the specification does not support the "...more limited definition of the term 'non-percutaneous' as meaning non-piercing or non-perforating..." Applicants disagree. As the Examiner points out, the term "non-percutaneous" in context of ductal cannulation or catheterization clearly means not piercing the skin. The penetration of a cannula or catheter through a ductal orifice cannot be characterized, as the Examiner has done, as being percutaneous. To suggest so would go against the common meaning that one skilled in the art of medical devices would understand. The Examiner must apply the meaning of the term in context of the field of invention, which in this case is the medical device area. The Examiner would certainly not consider the oral administration of a drug or insertion of a medical device through the oral cavity as being percutaneous. As an example using the Examiner's definition as a guide, a simple tongue depressor would be classified as a percutaneous device. This is clearly an inappropriate definition of the term. Thus, in the Applicant's application, the plain meaning of the term "non-percutaneous" refers to a device that is non-piercing or non-perforating as would be recognized by one skilled in the art. As such, there is no need for expressive written support in the specification.

For all the reasons stated above, Applicants request that the Examiner withdraw all rejections under 35 U.S.C. §112, First Paragraph.

The Rejections of Claims 36 Under 35 U.S.C. §112, First Second Should be Withdrawn:

Rejection of Claim 36 as lacking an antecedent basis in Claim 33 is obviated by the amendment to Claim 33 as described above. Applicants request that the rejection of Claim 36 under 35 U.S.C. §112, Second Paragraph be withdrawn.

The Rejection of Claims 33 and 36-39 Under 35 U.S.C. §103(a) Should be Withdrawn:

Claims 33 and 36-39 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Yoshimoto *et al.* in view of USP 5,681,543A and Canto *et al.* The examiner states

"It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to identify the location of lesions within a breast duct or breast ductal network for the purpose of conservatively excising the lesion and surrounding tissue by a process according to claims 33 and 36-39 because: (a) Yoshimoto et al. teaches the injection of gadolinium-DPTA into the breast duct to identify the location of such lesions by magnetic resonance imaging for the purposes of excising the lesions and surrounding tissue by conservative surgery; (b) '543 teaches gadolinium-DPTA; (c) '543 teaches or suggests that the targeted delivery of gadolinium using a diagnostic compound comprising a gadolinium-containing polymer complex and a targeting agent can be performed advantageously, since a targeted identifying agent targeted to lesions in the breast duct or breast ductal network concentrate in breast duct or breast ductal network and specifically bind lesions of the breast; and (d) Canto et al. teaches or suggests that washing to remove non-specific bound diagnostic agents can be performed by in vivo endoscopic procedures to improve the specificity of the test by reducing background noise, or the generation of non-specific, undesired signals."

The Applicants strongly disagree. Yoshimoto *et al.* does not teach or suggest a method for identifying the location of a lesion within a breast duct or breast ductal network. In fact, the experimental evidence presented in Yoshimoto *et al.* clearly demonstrates that galactography is insufficient at determining the exact location of a breast duct lesion. In the figure legend of Figure 1(B) of Yoshimoto *et al.* (page 88) it clearly states that "...it is difficult to know the exact location of the disease within the breast from these images." (emphasis added) Yoshimoto *et al.* simply does not teach or suggest a method of identifying the specific location of a lesion within a breast duct or breast ductal network. In fact, Yoshimoto *et al.* teaches away from the claimed

invention. Thus, Yoshimoto *et al.* cannot anticipate any of the pending claims because it does not disclose all of the limitations of the pending claims.

USP 5,681,543 (the '543 patent) teaches polymer-bonded complexing agents and pharmaceutical agents containing them for magnetic resonance imaging. The '543 patent does not teach or suggest the use of such complexing agents to identify the location of lesions within breast ducts. In fact, throughout the entire '543 document, there is but a single mention of breast cancer and that is in relation to the use of antibodies specific for a number of tumors including tumors of the gastrointestinal tract, breast, liver, bladder, gonads and of melanoma. The '543 patent does not teach or suggest a method to identify the specific location of a lesion within a breast duct or breast ductal network. Thus the '543 patent cannot anticipate any of the pending claims because it does not disclose all of the limitations of the pending claims.

Canto *et al.* teaches the use of methylene blue to stain specialized columnar epithelium in the esophagus of patients to identify adenocarcinomas. Canto *et al.* does not teach the use of methylene blue to stain breast duct lesions. In fact, Canto *et al.* states "[p]ositive staining was defined as blue-stained endoscopically normal esophageal mucosa that persisted despite vigorous water irrigation." (see page 2, column 2). Canto *et al.* teaches that methylene blue can be used to stain normal columnar epithelial which is located in the esophageal mucosa. Canto *et al.* does not teach that methylene blue can be used as a stain to distinguish breast cancer cells in breast ducts. Even assuming *arguendo* that methylene blue can be used to distinguish cancerous tissue from normal tissue, claim 33 includes the step of "allowing said delivered compound to specifically bind to at least one lesion within said at least one duct or ductal network; ...". Methylene blue does not specifically bind to breast cancer cells. Thus Canto *et al.* cannot anticipate any of the pending claims because it does not disclose all of the limitations of the pending claims.

In order to establish *prima facie* obviousness of a claim, all of the limitations of the claims must be taught or suggested by the prior art. *In re Royka* 490 F.2d 981 (CCPA 1974). For all the reasons stated above, the combination of Yoshimoto *et al.*, USP 5,681,543, and Canto *et al.* does not meet this standard is not sufficient to establish *prima facie* obviousness.

Applicants request that the rejection of Claims 33 and 36-39 under 35 U.S.C. §103(a) be withdrawn.

The Rejection of Claims 34 and 35 Under 35 U.S.C. §103(a) Should be Withdrawn:

Claims 34 and 35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Yoshimoto *et al.* in view of USP 5,681,543A, USP 4,628,027A, and Canto *et al.*, and in further view of USP 6,168,779. Applicants submit that the claims are neither anticipated by Yoshimoto *et al.* (as discussed above) nor are they made obvious by the cited references. Yoshimoto *et al.* does not teach or suggest a method to identify the specific location of a lesion within a breast duct or breast ductal network. Thus Yoshimoto *et al.* cannot anticipate any of the pending claims because it does not disclose all of the limitations of the pending claims.

As discussed above, neither the Canto *et al.* reference nor the '543 patent teach the presently claimed invention. Combining the Canto *et al.* reference and/or the '543 patent with references that teach monoclonal antibodies against connective tissue proteins (such as the cited reference U.S. Patent No. 4,628,027) or methods for identifying ductal orifices (such as the cited reference U.S. Patent No. 6,168,779) cannot make up for the deficiencies of the Yoshimoto *et al.* reference with respect to the claimed method for identifying the location of a lesion within a breast duct or breast ductal network.

In view of the arguments presented above, applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

CONCLUSION

In light of the amendments and arguments presented above, Applicants respectfully submit that the claims are in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.006011.

Respectfully submitted,

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Invention: **Methods for Identification, Diagnosis and Treatment of Breast Cancer**

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Amendment after Final

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